EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

AFFIDAVIT OF ANNE WILSON

I, Anne Wilson, being duly sworn, state as follows:

I. INTRODUCTION

1. I have been asked to review Defendants' Motion for a Protective Order Relieving Defendants of Responding to a Provision in Defendant's Fact Sheet Requiring Production of Device History Records as well as the Declaration of Mary Carmel Lowe, both of which are dated November 24, 2015. I have reviewed these documents and they concern Ethicon's argument that it is an undue burden for Ethicon to produce the device history records for Wave 2 and any subsequent wave(s) absent a showing of need.

II. QUALIFICATIONS

2. I received a Bachelor of Science in Biomedical Engineering from Vanderbilt University in 1985, and a Master of Business Administration from the University of Colorado in 1991.
3. I currently hold certifications as Certified Quality Auditor, Certified Quality Engineer, and Certified Quality Manager through the American Society for Quality. I also am a Certified Quality System Lead Auditor through Exemplar Global (formerly RABQSA International), and a Registered Quality Assurance Professional in Good Laboratory Practice through the Society of Quality Assurance.

4. In 2000, I founded QA Consulting, Inc. where I continue to serve as CEO. I consult with medical device manufacturers to develop and implement compliant solutions for their quality practices. I have created, customized and implemented quality management systems for over 25 manufacturers including numerous implantable devices. I have completed 100+ supply chain / internal audits to U.S and International Standards and been involved in over fifty (50) 510k applications and therefore am familiar with the requirements relating to clearance of a medical device.

5. My 30 years of experience as a Biomedical Engineer in quality assurance, ranging from design concept and research and development through manufacturing/production and post-market surveillance for Class I, II, and III medical devices has afforded me expert knowledge of medical device industry regulations and standards, including but not limited to Title 21 – Food and Drugs of the Code of Federal Regulations, particularly Section 820, Quality System Regulation, Section 803, Medical Device Reporting and Section 58, Good Laboratory Practice for Nonclinical Laboratory Studies, as well as ISO Standard 13485, Medical Devices - Quality management systems – Requirements for regulatory purposes, ISO 14971, Medical Devices – Application of risk management to medical devices, and ISO 9001, Quality management systems – Requirements.

III. OPINIONS

6. I offer two opinions in this affidavit: (1) Ethicon was required to compile and maintain the information requested by industry standards and federal regulation; therefore, retrieval and production should not impose any additional or undue burdens on them; and (2) the information contained in the Design History File and the Device Master Records is relevant and necessary information to establish and understand whether Ethicon complied with

industry standards for the reporting, trending, and analysis of adverse events and whether complaints and adverse events are caused by design issues or manufacturing issues.

7. Device master records (DMR) and device history records (DHR) are two specific types of records required by 21 CFR §820.181/ ISO 13485 § 4.2.1, §7.1 and 21 CFR §820.184/ ISO 13485 § 7.5.1.1 respectively. The DMR defines the device specific *recipe* for producing a device whereas the DHR shows that the *recipe* used to make the lot/ batch of devices was followed. The DHR demonstrates that device(s) were manufactured in accordance with the DMR. "Theoretically, if the DMR is constructed correctly, the contents could be taken from one manufacturing facility to another and could be used to produce a device that would be identical to the one produced at the original facility."[1] Per the regulations defined herein, the DMR includes or references:

   a. Device specifications including drawings, component specification, written specifications (including software and material composition)

   b. Production process specifications including production methods, equipment and environmental requirements

8. All medical device manufacturers are required to keep records concerning activities performed by that manufacturer with respect to all products, including the DMR and DHR.[2] In my experience, given the use of computers and scanning capabilities, records required to be maintained are currently often available within an hour or two; however there are industry expectations for both small companies that utilize manual records with off-site storage as well as large, worldwide corporations, such as Ethicon. These records are

[1] The Quality System Compendium CGMP Requirements and Industry Practice, AAMI Third Edition, page 170.
[2] ISO 9000:2005 Quality management systems—Fundamentals and vocabulary.

required to be reasonably accessible for review by the FDA during the course of FDA inspections, which often are conducted in 4 days.[3]

9. As with the case of Ethicon Neuchatel Switzerland, a "foreign manufacturer who maintains records at a remote site is expected to produce any requested records within two working days."[4]

10. Based on these expectations as well as my experience, records archiving of for any medium to large manufacturer needs to be a well thought out, thorough and practical system with built in mechanisms anticipating retrieval needs. Off-site document storage is generally coupled with an in house database or index defining where each record type is stored by key fields such as lot number, sterilization lot, or expiration date to facilitate timely retrieval. All documents are also required to be legible and stored to minimize deterioration.

11. If Ethicon is in compliance with these requirements, retrieval of the information requested should not require any undue burden or expectation beyond that which they are already doing as a medical device manufacturer (as opposed to a defendant in litigation). This information in question is information that should be readily accessible for review by the FDA within a 4 day inspection and therefore should not impose any undue burden to Ethicon to comply with the request.

12. If Ethicon is unable to produce the information as claimed in the briefing and affidavit, that means that Ethicon is most likely not in compliance with industry standards and regulations concerning the storage and retrieval of the requested information.

[3] The Quality System Compendium CGMP Requirements and Industry Practice, AAMI Third Edition, page 165.
[4] Id.

13. Furthermore, the information contained in the DHR is valuable information to understand the manufacturing operations and compliance by a medical device manufacturers and how the medical device is actually performing. Specifically, the DHR is intended to show that each batch, lot or unit are manufactured in accordance with the DMR. It is defined as "a compilation of records containing the production history of a finished device."[5] "The DHR is used to "facilitate failure investigation and corrective or preventative actions"[6] as well as to provide traceability information.

14. Adherence to product conformance and performance requirements as found in the DHR are required to be routinely analyzed to provide early warning signs of product related issues that could arise for users and as an input for corrective/ preventive (CAPA) actions per 21 CFR 820.100 and ISO 13485 § 8.4, §8.5.2 and §8.5.3. The trending or data analysis is also an input to Management Review as defined in 21 CFR §820.20 and ISO 13485 § 5.6.2 (c). This requirement ensures that Top Management is aware of existing or emerging issues. Trending of data extracted from the DHR on process performance, product nonconformances, materials and suppliers are critical to the early identification of quality problems that may require corrective or preventive actions in order to maintain the effectiveness of the QMS as stated ins ISO 13485 §8.1.

15. Similarly, the DHR "serves as the basis for investigating complaints and taking corrective action because it provides a record of any shifts, changes, or variances in the manufacturing process that may result in problems with finished devices."[7] In my experience both in industry and as a consultant, the first two actions that are taken in response to a complaint

[5] 21 CFR §820.184.
[6] The Quality System Compendium CGMP Requirements and Industry Practice, AAMI Third Edition, page 172.
[7] Id..

are: 1) attempt to obtain any missing information from the complainant such that a true, detailed evaluation and investigation can be performed, 2) pull the DHR and review it to ensure compliance with the DMR and that no process or inspection anomalies exist. In other words, medical device manufacturers such as Ethicon are required to determine whether the cause of the complaints they know or should know about are problems with the manufacturing process through a review of the DMR.

16. The DHR is the only evidence that demonstrates how the lot/ batch was built and can demonstrate that the device was manufactured in accordance with defined materials, procedures, and drawings such that they met specifications per predefined acceptance criteria at the time of release for sale. In the absence of this information, no one can determine whether there are problems in the manufacturing process for particular lots or groups of the devices.

Dated: _____, 2015

Anne Holland Wilson

Digitally signed by Anne Holland Wilson
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Date: 2015.12.09 15:39:36 -06'00'

Anne Wilson